

Application No.: 10/603,952

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**REMARKS**

The Office Action dated February 17, 2006 has been reviewed and the Examiner's comments considered. Claims 1-11 and 14-24 are pending in this application. Claims 25-26 are canceled by this amendment, having been withdrawn from consideration by the Examiner as being directed to a non-elected invention. Claims 1, 11, 18, 19, 21 and 23 are amended herein. Support for the amendments can be found in the originally filed specification, for example, in FIGS. 9-13 and paragraphs [0031] - [0033]. No new matter or issues have been introduced.

**§ 112, Second Paragraph**

Claims 1-17, 21 and 22 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, with respect to claim 1, the Examiner found the limitation of the opening being "larger than the tubular portion" to be vague and indefinite and suggested the use of "cross-sectional area" for comparison purposes. While Applicants disagree with the Examiner's assessment, in view of the desire for compact prosecution, Applicants have amended claim 1 to include the suggested "cross-sectional area" language proposed by the Examiner. Also, the Examiner found claim 21 to be unclear due to the use of the word "smaller" to compare tubular diameter portions. Again, Applicants disagree with the Examiner's assessment of indefiniteness but have amended claim 21 to recite the diameters of respective tubular diameter portions in the interest of compact prosecution. Applicants have reviewed the pending claims and believe that all comply with 35 U.S.C. § 112, second paragraph and, hence, request withdrawal of this rejection.

**Horiguchi**

Claims 1, 3, 7, 14, 16, 18, 19 and 21 stand rejected under 35 U.S.C. § 102(e) as being anticipated by USPN 5,755,779 to Horiguchi. Claims 2, 4-6, 8-11, 15, 17, 20 and 22-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Horiguchi. Applicants respectfully traverse these rejections.

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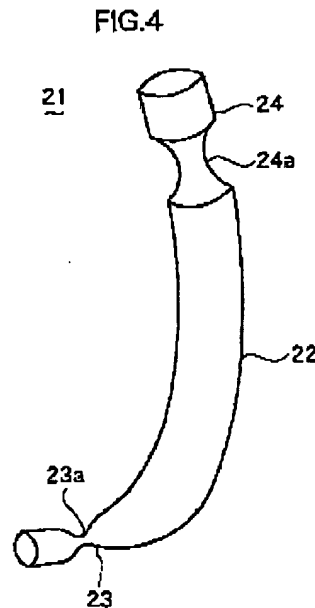
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As amended, independent claim 1 recites, *inter alia*, an “an enlarged chamber with a non-circular open end perimeter outlining a cross-sectional area larger than a cross-sectional area of the tubular portion at the first diameter.” Similarly, claims 18 and 21 recite, *inter alia*, “an enlarged chamber with a non-circular open end perimeter outlining a cross-sectional area larger than a cross-sectional area of the first diameter portion.”

Horiguchi shows and describes a blood stream adjuster for a blood vessel for bypass 21 . In FIG. 4, shown below, Horiguchi shows a blood stream adjuster 23, having a stricture portion 23a, arranged inside one part of a main body 22 (col. 4:56 to col. 5:10).



However, Horiguchi does not show or describe at least an enlarged chamber with a non-circular open end perimeter outlining a cross-sectional area larger than a cross-sectional area of the first diameter portion as claimed. Hence, Horiguchi does not anticipate claims 1, 18 or 21 and claims 1, 18 and 21 are patentable in view of Horiguchi. Claims 2-11, 14-17, 19-20 and 22 dependent on claims 1, 18 and 21 are also patentable in view of Horiguchi because they depend on a patentable claim, and also recite other features not shown or described in Horiguchi.

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With respect to claim 23, the Examiner does not specify why it would have been obvious to one of ordinary skill in the art to modify the blood vessel for bypass 21 to have an "enlargement including an open distal end with a diameter larger than a diameter of the tubular part" as claimed. Applicants respectfully submit that a *prima facie* case of obviousness has not been met because at least one of the three required criteria (*see* p. 2100-135, MPEP 2143, 8th Ed., Rev. 3, August 2005) is missing. In particular, the prior art reference utilized for purposes of obviousness must teach or suggest all of the claim limitations. However, there is no mention in Horiguchi of an enlargement, and certainly no mention of an enlargement including an open distal end with a diameter larger than a diameter of the tubular part. Horiguchi simply shows and describes a modification to a blood vessel for bypass through the insertion of blood stream adjuster. There is no mention of modifications to an end of the blood vessel for bypass, such as the enlargement claimed. Therefore, all of the claim limitations are not taught or suggested and, hence, Horiguchi does not render claim 23 obvious under 35 U.S.C. § 103(a). Thus, claim 23, and dependent claim 24, are patentable over Horiguchi.

#### Gore Advertisement

Claims 23 stands rejected under 35 U.S.C. § 102(b) as being anticipated by the Gore advertisement. Applicants respectfully traverse this rejection.

The caption on the Gore advertisement reads, "Rings have been removed from the end of an FEP-Ringed GORE-TEX Vascular Graft with Removable Rings to facilitate the creation of a beveled anastomosis." The Examiner states that the ePTFE structure pictured "comprises an enlargement at a distal end because of the ring, which defines an outer diameter larger than an outer diameter of the tubular part." Claim 23, however, requires "a continuous expanded polytetrafluoroethylene structure" comprising "an enlargement at the distal end of the tubular part" the enlargement "defining an enlarged chamber." The Gore advertisement shows a graft with FEP rings arranged over an outer surface over its length, the picture showing the FEP rings actually removed from the distal end. Thus, there is no enlargement at the distal end of a tubular part of a continuous expanded polytetrafluoroethylene structure shown, and certainly no enlarged chamber.

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Accordingly, the Gore Advertisement does not describe each and every element as set forth in claim 23 and, consequently, the Gore Advertisement does not anticipate claim 23. Hence, claim 23 is patentable over the Gore Advertisement.

**Lunn**

Claims 1-5, 7-11 and 14-17 stand rejected under 35 U.S.C. § 102(e) as being anticipated by USPN 5,476,506 to Lunn. Claims 6 and 23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lunn. Applicants respectfully traverse these rejections.

Lunn is directed to a bi-directional crimped graft for placement within a blood vessel to span a diseased portion thereof, the graft having ends that are sufficiently elastic such that they can be affixed to a stent when the stent is unexpanded and then increased in diameter, together with the stent as the stent is expanded toward the walls of the blood vessel (col. 1:60-65, col. 2:13-21). With respect to independent claim 1, Lunn does not include "a generally uniform surface and a first diameter that tapers to a smaller second diameter adjacent said end formation" nor "an enlarged chamber with a non-circular open end perimeter" as claimed. Hence, Lunn does not anticipate claim 1 and claim 1 is patentable in view of Lunn. Claims 2-11 and 14-17 dependent on claim 1 are also patentable in view of Lunn because they depend on a patentable claim, and also recite other features not shown or described in Lunn.

With respect to claim 23, Applicants submit that a *prima facie* case of obviousness is not established for at least two reasons: 1) Lunn does not teach or suggest all of the claim limitations, and 2) there is no motivation or suggestion to modify the graft of Lunn.

First, Lunn does not show or describe a continuous expanded polytetrafluoroethylene structure with a generally uniform surface as claimed. Instead, Lunn shows and describes a graft with a central portion with a series of circumferential crimps to "provide the central portion with a great degree of freedom in extending the central portion to a selected length to conform to the site of application" (col. 3:48-53), and end portions with a series of longitudinally extending crimps that graft "provide the end portion with a great degree of freedom in expanding the end portion to a

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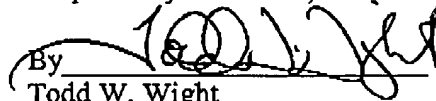
selected diameter" (col. 3:10-15). Thus, Lunn does not teach or suggest all of the claim limitations. Second, the intended purpose of the Lunn graft is to provide a graft that offers "great freedom of both longitudinal and radial expansion at the central and end portions, respectively" (col. 2:6-8). To modify Lunn to remove the crimps would therefore render the graft of Lunn unsuitable for its intended purpose. Hence, there is no motivation to modify the graft of Lunn. Therefore, a *prima facie* case of obviousness has not been established, at least because Lunn does not teach or suggest all of the claim limitations and there is no motivation or suggestion to modify the graft of Lunn. Thus, claim 23 is patentable in view of Lunn

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 297912001602. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 17, 2006

Respectfully submitted,

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